

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

WATERS MEDICAL SYSTEMS LLC

2112 15th Street Northwest,

ROCHESTER, MN 55901 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

Kit de perfusion, préservation/transport pour greffons rénaux

Kidney donor-organ preservation/transport perfusion set

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000027-8-S2, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T000027-8-S2, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : October 19th, 2018 (included)

Valable jusqu'au / Expiry date : December 1st, 2019 (included)



On behalf of the President

Béatrice LYS

Technical Director

Identification des dispositifs / Identification of devices

Product Name	Model Reference Number	MD Class
100-DCM Cassettes (sterile)	0012691.000	IIa
50-DCM Cassettes (sterile)	0012591.000	
Case of four DCM 100 Cassettes (dual kidney)	0008190.000	
Case of four DCM 50 Cassettes (single kidney)	0008090.000	
Triple Artery Cannulae (sterile)	0015093.001	
Trident Artery Cannulae (sterile)	3920140.023	
3mm Teflon Perfusion Cannulae (sterile)	3910141.003	
4mm Teflon Perfusion Cannulae (sterile)	3910141.004	
5mm Teflon Perfusion Cannulae (sterile)	3910141.005	
6mm Teflon Perfusion Cannulae (sterile)	3910141.006	
7mm Teflon Perfusion Cannulae (sterile)	3910141.007	
8mm Teflon Perfusion Cannulae (sterile)	3910141.008	
9mm Teflon Perfusion Cannulae (sterile)	3910141.009	
10mm Teflon Perfusion Cannulae (sterile)	3910141.010	
WAVES Control Unit	3900042.000	
WAVES Cassette Module WCM (sterile)	3930005.014	
WAVES Transport Bag	3930140.007	
WAVES Disposable Drape (sterile)	3910140.001	
WAVES Trident Artery Adapter (sterile)	3920140.023	

Ce certificat couvre les sites suivants :
This certificate covers the following sites:

Waters Medical Systems, LLC
 2112 15th Street Northwest
 Rochester MN 55901 USA

Activités effectuées en ce site / Activities performed on this site:

Conception, fabrication & contrôle final
Design, manufacturing and final control

1 site / 1 site



GMED 0459

On behalf of the President
Béatrice LYS
 Technical Director